

**§ 508.19 Establishment of requirements for exemption from section 404 of the act.**

(a) Whenever the Commissioner finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with microorganisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he shall promulgate regulations in subpart B of this part establishing requirements and conditions governing the manufacture, processing, or packing of the food necessary to protect the public health. Such regulations may be proposed by the Commissioner on his own initiative or in response to a petition from any interested person pursuant to part 10 of this chapter.

(b) A manufacturer, processor, or packer of a food for which a regulation has been promulgated in subpart B of this part shall be exempt from the requirement for a permit only if he meets all of the mandatory requirements and conditions established in that regulation.

[41 FR 38637, Sept. 10, 1976, as amended at 42 FR 4717, Jan. 25, 1977; 42 FR 15675, Mar. 22, 1977]

**Subpart B—Requirements and Conditions for Exemption From or Compliance With an Emergency Permit**

**§ 508.35 Thermal processing of low-acid animal foods packaged in hermetically sealed containers.**

(a) Inadequate or improper manufacture, processing, or packing of thermally processed low-acid foods in hermetically sealed containers may result in the distribution in interstate commerce of processed foods that may be injurious to health. The harmful nature of such foods cannot be adequately determined after these foods have entered into interstate commerce. The Commissioner of Food and Drugs therefore finds that, in order to protect the public health, it may be necessary to require any commercial processor, in

any establishment engaged in the manufacture, processing, or packing of thermally processed low-acid foods in hermetically sealed containers, to obtain and hold a temporary emergency permit provided for under section 404 of the Federal Food, Drug, and Cosmetic Act. Such a permit may be required whenever the Commissioner finds, after investigation, that the commercial processor has failed to fulfill all the requirements of this section, including registration and the filing of process information, and the mandatory portions of part 507 of this chapter. These requirements are intended to ensure safe manufacture, processing, and packing procedures and to permit the Food and Drug Administration to verify that these procedures are being followed. Such failure shall constitute a prima facie basis for the immediate application of the emergency permit control provisions of section 404 of the act to that establishment, pursuant to the procedures established in subpart A of this part.

(b) The definitions in § 507.3 of this chapter are applicable when such terms are used in this section.

(c) *Registration and process filing—(1) Registration.* A commercial processor when first engaging in the manufacture, processing, or packing of thermally processed low-acid foods in hermetically sealed containers in any state, as defined in section 201(a)(1) of the act, shall, not later than 10 days after first so engaging, register with the Food and Drug Administration on Form FD-2541 (food canning establishment registration) information including (but not limited to) his name, principal place of business, the location of each establishment in which such processing is carried on, the processing method in terms of the type of processing equipment employed, and a list of the low-acid foods so processed in each such establishment. These forms are available from the Center for Food Safety and Applied Nutrition, (HFS-565), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or at any Food and Drug Administration district office. The completed form shall be submitted to the Center for Food Safety and Applied Nutrition, (HFS-617), Food and Drug